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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,214	07/09/2001	Gordon L. Amidon	PSL-10202/39	6240

7590 10/16/2002

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/901,214

Applicant(s)

AMIDON ET AL.

Examiner

San-ming Hui

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1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

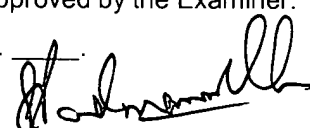
NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-14.Claim(s) withdrawn from consideration: 15-20.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


SREENI PADMANABHAN
PRIMARY EXAMINER

10/13/02

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ADVISORY ACTION

Continuation of 5):

The outstanding rejections under 35 USC 112, second paragraph set forth in the previous office action mailed July 2, 2002 still remain for the following reason:

The limitation "the ratio of the initial mass ... such that the drug particle is solubilized ... to an extent greater than 0.001 milligram per milliliter" in claim 1 and 12 renders the claim indefinite because it is unclear what ratio of the initial mass of the particle and the diffusional boundary layer would be so that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter. Applicant's remarks regarding an example, Equation 2, in page 5, line 12 of the instant specification have been considered but are not found persuasive. Firstly, the specification defines the relationship between the volume of the diffusional boundary layer and the mass of the drug particle, but it does not expressly disclose what ratio of the initial mass of the particle and the diffusional boundary layer needs to be in order for the solubility of the drug particles to be greater than 0.001 mg/ml. Secondly, the specification merely states Equation 2 as an example, which indicates that the ratio could have been represented by other formulae. Therefore, it is not clear what the ratio would be in order for the solubility of the drug particles to be greater than 0.001 mg/ml. Thirdly, according to Equation 2, $M_P/V_{BL} = C_{SAT}$, and if the C_{SAT} is greater than 0.001, M_P/V_{BL} will be greater than 0.001mg/ml. However, the claims herein recite ratio that is beyond the range of 0.001 and above. Actually, the ratio, as herein claimed, covers any ratio of the initial mass of the particle and the diffusional boundary layer.

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Applicant rebuttal argument filed September 17, 2002 averring Amidon et al. not teaching the rate of release of a pharmaceutical compound from an inventive delivery vehicle is greater than when bulk powder is used, as shown in Figure 3, page 10, line 5 of the instant specification, have been considered but are not found persuasive. Amidon et al. also show exactly that in Figure 2.

No unanswered rebuttal arguments are seen to be present herein. The outstanding rejections set forth in the previous office action mailed July 2, 2002 still remain since no amendments to the claims are filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui
October 7, 2002